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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,992	07/15/2003	Steven Hefeneider	00-617-F	8235

7590 02/10/2006

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/619,992	Applicant(s) HEFENEIDER ET AL.	
Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/05/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 11/30/2005 has been entered in full. Claims 1-6 have been amended. Claims 1-6 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The objection to the title of the application is withdrawn in view of the amendment to the specification.

Information Disclosure Statement

The information disclosure statement filed on 12/05/2005 has been considered by the Examiner.

Claim Rejections under 35 USC § 112, 1st paragraph

The rejection of claims 1-6 under 35 U.S.C. 112, first paragraph for scope of enablement is maintained because the specification, while being enabling for a human cell surface DNA receptor (DNA-R) set forth in SEQ ID NO: 2, a DNA binding fragment comprising amino acids 1-575 of the amino acid sequence of SEQ ID NO: 2, or a soluble human DNA-R with the amino acids 1133-1171 of SEQ ID NO: 2 are deleted,

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does not reasonably provide enablement for their derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At page 5 of Applicants' response filed on 11/30/2005, Applicants argue that the claimed invention is limited to a homogenous composition or a cell membrane preparation having the amino acid sequence of SEQ ID NO: 2. Applicants submit that any potential derivative, like the original composition, is limited to a composition having the amino acid sequence of SEQ ID NO: 2.

Applicants' argument has been fully considered, but is not deemed to be persuasive because it is not clear whether the claims, as written, are limited to a composition having the amino acid sequence of SEQ ID NO: 2. If the claims are amended to clearly recite such a limitation for the composition, the rejection will be withdrawn.

Claim Rejections under 35 USC § 112, 2nd paragraph

The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph is maintained.

At page 5 of Applicants' response filed on 11/30/2005, Applicants argue that Applicants have amended the claims to specify that the molecular weight are predicted from the amino acid sequence as set forth in the Sequence listing and do not account for any post –translational modifications. The Examiner notes that the amended claims have resolved this issue. However, the other issue raised in the previous action, which

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renders the claims indefinite, still remains. That is, it is unclear whether the recited limitation, "having a molecular weight ..." in each claim, limits DNA-R, its derivatives, or both, rendering the claim indefinite. It is also suggested that the claims be amended to provide the complete name for DNA-R, such as "a mammalian cell surface DNA receptor (DNA-R)".

Claim Rejections under 35 USC § 102 (b)

The rejection of claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Fantin et al. (*J. Biol. Chem.* 273:10726-10732, 1998) or by Hefeneider et al. (*J. Invest. Dermatol.* 94:79S-84S, 1990) is maintained.

At the 3rd paragraph of page 6 of Applicants' response filed on 11/30/2005, Applicants argue that there is no evidence of record that membranes prepared according to the methods disclosed by Fantin et al. would contain a functional DNA-R as disclosed in the instant specification. Applicants' argument has been fully considered, but is not deemed to be persuasive because the human embryonic kidney 293 cells express the claimed cell surface DNA receptor and a membrane preparation from the human embryonic kidney 293 cells inherently comprises the claimed cell surface DNA receptor.

At the bottom of page 6 of Applicants' response filed on 11/30/2005, Applicants argue that Hefeneider et al. do not teach explicitly that the claimed DNA-R protein is indeed expressed in PBMC, nor do they teach that the claimed DNA-R protein is present in the membrane of PBMC. Applicants' argument has been fully considered, but is not

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deemed to be persuasive because human peripheral blood mononuclear cells in nature express the claimed cell surface DNA receptor and a membrane preparation from the PBMC inherently comprises the claimed cell surface DNA receptor.

It is noted that once a reference teaching product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
February 6, 2006